REMARKS

Claims 39-50, 62-65, and 78-89 are currently pending in the application. Claims 45-47, 78, 80-82 have been withdrawn as being directed to non-elected groups. Claims 43, 63 and 83 have been canceled. Claims 39, 41, 62, 85, and 86 have been amended. Support for the amendments to the claims may be found throughout the specification and claims as originally filed. Claim 41 has been amended to incorporate claim 43. Support for the amendments to independent claims 39, 62 and 86 may be found, for example, in the abstract, the original claims and the specification, for example, Page 3, lines 15-18. No new matter has been added.

Amendment or cancellation of claims should not be construed as an acquiescence or surrender of any subject matter. The amendments are being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicants reserve the right to prosecute the originally filed claims further, or similar ones, in the instant or subsequently filed patent applications.

OBJECTION TO THE OATH/DECLARATION

The Office Action indicates that the Oath/Declaration is defective. In particular, a new Oath/Declaration in compliance with 37 C.F.R. 1.67(a) is required because it does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 C.F.R. 1.56. Applicants are in the process of obtaining a new Oath/Declaration in compliance with 37 C.F.R. 1.67(a). Applicants will submit the new Oath/Declaration as soon as it is available.

OBJECTION TO THE SPECIFICATION

The Examiner has objected to the specification for the following informalities:

(A) The Examiner has objected to the specification as lacking section headings to identify the different portions of the disclosure.

Applicants have amended the specification to insert the section headings.

(B) The Examiner objects to the specification for failure to comply with 37 C.F.R. 1.821. The specification has been amended to insert the required SEQ ID NOs associated with each of the listed sequences.

A Statement to Support Filing and Submission in Accordance with 37 C.F.R. §§ 1.821-1.825, a paper copy of the Sequence Listing, and a computer readable version of the Sequence Listing is consistent with the specification as submitted concurrently herewith. No new matter has been added.

(C) The Examiner has objected to the specification as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Examiner contends that the specification fails to provide proper written description for the detection of *Proteus spp.*, *Enterobacter spp.*, *Enterococcus spp.*, *Klebsiella spp.*, and *Pneumococci* as recited in claim 41. Additionally, it is contended that the specification does not provide proper written description for kits as recited in claims 62-65, 78, 79, 81, 83-85, and 89.

Applicants may rely on the abstract and original claims to provide appropriate written description for claimed subject matter. *See* MPEP § 608.01 (l) ("In establishing a disclosure, applicant may rely not only on the description and drawing as filed but also on the original claims if their content justifies it.") and MPEP § 608.01 (b) ("the abstract of the disclosure has been interpreted to be a part of the specification for the purpose of compliance with paragraph 1 of 35 U.S.C. 112."). The detection of *Proteus spp.*, *Enterobacter spp.*, *Enterococcus spp.*, *Klebsiella spp.*, and *Pneumococci* as recited in claims 41 and 85 are specifically supported by original claim 3, page 1, lines 11-14, Table 1, and the abstract of the specification. The detection of *Proteus spp.* is supported on page 5, lines 11-18 of the specification. The detection of *Enterobacter spp.* is supported on page 5, lines 36-38; page 8, lines 26-28; and page 9, lines 23-25 of the specification. The detection of *Enterococcus spp.* is supported on page 6, lines 21-23 and page 6, lines 35-37 of the specification. The detection of *Klebsiella spp.* is supported on page 5, lines 24-30 of the specification. The detection of *Pneumococci* is supported on page 6, lines 5-7, 17-19, and 31-33; page 7, lines 33-43; and page 8, lines 1-15 of the specification. The kits as recited in claims 62-65 are specifically supported by original claims 25-27 and the abstract of the specification.

(D) The Examiner has objected to the Article 34 amendment under 35 U.S.C. 132(a) as introducing new matter.

Applicants have amended the specification to remove the Article 34 amendments.

Based on the foregoing, reconsideration and withdrawal of the objections to the specification are respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 112, 1

Claims 39-44, 46, 48-50, 62-65, 78, 79, 81, and 83-89 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. The rejected claims allegedly contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner acknowledges that the original disclosure provides support for oligonucleotide primers consisting essentially of SEQ ID NO: 1 and SEQ ID NO: 2.

The Examiner, however, contends that the original disclosure does not provide support for the kits recited in claims 62-65, 78, 79, 81, 83-85 and 89, "because only kits comprising primers **or** probes are taught in the original disclosure

As amended, independent claims 39, 62 and 86 specify that the first primer consists essentially of an oligonucleotide as shown in SEQ. ID. NO: 1; and the second primer consists essentially of an oligonucleotide as shown in SEQ. ID. NO: 2. Claim 62 has been further amended to delete reference to oligonucleotide probes.

As amended, the claims obviate this ground of rejection. Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 39-44, 46, 48, 49, 62, 64, 65, 78, 79, 81, and 83-89 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bergeron et al, in view of Gurtler et al. Brosius et al. and/or Lowe et al..

The Examiner contends that Bergeron "teaches designing universal amplification primers from the gene encoding the 23S rRNA." The Examiner acknowledges that Bergeron does not specifically teach the primers set forth in SEQ ID NOs: 1 and 2." The Examiner relies on Gurtler as teaching that the conserved regions of the 23S rRNA gene that are targeted by primers of SEQ ID NO: 1 and SEQ ID NO: 2. The Examiner further relies on Brosius as teaching the nucleic acid sequence of the 23S rRNA gene from *E. coli*, which contains SEQ ID NOs: 1 and 2. Finally, the Examiner relies on Lowe as teaching a computer program for designing all possible oligonucleotide primers from a known nucleic acid sequence based on a set of user-specificed conditions. Based on the combined teachings, it is contended that:

> *[I]t would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to practice the methods of Bergeron using a primer having a sequence as shown in SEQ ID NO: 1, a primer having a sequence as shown in SEQ ID NO: 2, and an oligonucleotide probe having a sequence as shown in SEQ ID NO: 4...the ordinary artisan would have reasonable expectation of success, in pursuing this finite number of possible oligonucleotides suggested by the prior art of Gurtler, since, as evidence by Lowe, methods for designing and synthesizing oligonucleotide primers and probes were well-known in the art at the time of invention, and since, as evidenced by Brosius, the complete 23S rRNA gene sequence from E. coli was known in the art at the time of the invention.*

A reference must be considered as a whole, including disclosures that teach away from the claimed invention. M.P.E.P. § 2142.02. Under *KSR*, "teaching away" still provides evidence of non-obviousness. *See* 127 S.Ct. at 1745. "[P]roceeding contrary to accepted wisdom in the art is evidence of nonobviousness." M.P.E.P. §2145 (citing *in re Hedges*, 783 F.2d 1083 (Fed. Cir. 1986)). If when combined, the references "would produce a seemingly inoperative device," then they teach away from their combination. *Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). *See also, In re Fritch*, 972 F. 2d 1260, 1265 n. 12 (Fed. Cir. 1982) ("A

proposed modification [is] inappropriate for an obviousness inquiry when the modification render[s] the prior art reference inoperable for its intended purpose.").

Bergeron expressly teaches away from generating amplicons from bacterial ribosomal genes (16S or 23S) and probing the amplicons with bacterial species specific probes. In particular, Bergeron states that "the strategy from the present invention is different, simpler and more rapid because it allows the direct amplification of species-specific, genus-specific or universal bacterial targets using oligonucleotides derived from genomic DNA fragments ***other than the 16S rRNA genes*** or from antibiotic resistance DNA sequences which are derived either from the genome or from extrachromosomal elements." (*Emphasis added*) *Bergeron* at col. 3, ll. 5-12. As noted in Bergeron, primer sequences derived from "highly conserved regions of the bacterial 16S rRNA gene were used to provide an internal control for all PCR reactions" to detect bacteria in a sample. *Bergeron* at col. 19, ll. 33-37. Thus, based upon a reading of Bergeron, one of skill in the art would not use primers to amplify bacterial genes encoding ribosomal subunits.

Gurtler does not make up for the deficiencies of the primary reference. In fact, Gurtler also teaches away from the instant claims. Although, as pointed out by the Examiner, Gurtler teaches "[a] primer to regions 6, 8, and 9 should also be appropriate (to generate an amplicon that could be used to probe oligonucleotides) given the level of sequence conservation of the region (Table 1)." *Gurtler* at page 9. However, Gurtler specifically points out that "these have not been successful in detecting spacer variation in the instances in which they have been used." *Id.* Thus, a reading of Gurtler would not lead a skilled artisan to predict, with any expectation of success, that primers to the conserved regions of 23S rRNA would produce amplicons that could be labeled and used as probes against bacterial-specific oligonucleotides.

Brosius and Lowe also do not make up for the deficiencies in the teachings of Bergeron and Gurtler. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 50 and 63 were separately rejected under 35 U.S.C. § 103(a) as being unpatentable over Bergeron et al. in view of Gurtler et al, Brosius et al. and/or Lowe et al.and further in view of Kawasaki et al..(which is cited as teaching reverse dot blot hybridization." Claim 63 has been cancelled, thereby obviating the rejection as it pertains to that claim.

As explained above, with respect to claim 39, from which claim 50 depends, the combined teaching of Bergeron, Gurtler, Brosius, and/or Lowe do not teach or suggest the instant claimed method. Kawasaki et al., does not remedy the deficiencies of these references.

Accordingly, the rejections under 35 U.S.C. § 103(a) should be withdrawn.

CONCLUSION

Early and favorable consideration of the application is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at (617) 832-1000. If any fees are due, the Commissioner is hereby authorized to credit any overpayment or charge any deficiencies to **Deposit Account No. 06-1448, IMA-031.01.**

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Respectfully submitted,

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